## AMENDED IN ASSEMBLY MAY 16, 2002 AMENDED IN ASSEMBLY MAY 1, 2002 AMENDED IN ASSEMBLY APRIL 1, 2002

CALIFORNIA LEGISLATURE—2001-02 REGULAR SESSION

## ASSEMBLY BILL

No. 2191

## **Introduced by Assembly Member Migden**

February 20, 2002

An act to amend Sections 56.05, 56.10, 56.101, 56.11, and 56.12, and 56.37 of, and to add Section 56.102 to, the Civil Code, relating to medical information.

## LEGISLATIVE COUNSEL'S DIGEST

AB 2191, as amended, Migden. Medical records: confidentiality.

(1) Existing law, the Confidentiality of Medical Information Act, prohibits providers of health care, health care service plans, and contractors, as defined, from disclosing medical information regarding a patient, without first obtaining authorization, except in specified instances.

This bill would also specifically prohibit pharmaceutical companies, as defined, or agents or representatives of pharmaceutical companies, from disclosing medical information regarding a patient, without first obtaining authorization, *except as specified*.

(2) The Confidentiality of Medical Information Act also prohibits providers of health care, health care service plans, and contractors from requiring a patient, as a condition of receiving health care services, to sign an authorization, release, consent, or waiver permitting the disclosure of medical information, except as specified, and further

AB 2191 — 2 —

requires these entities to maintain, dispose of, and release medical information and records in a manner that preserves confidentiality, according to certain procedures.

This bill would-also specifically prohibit pharmaceutical companies, or agents or representatives of pharmaceutical companies, as defined, from requiring a patient, as a condition of receiving health services, including pharmaceuticals, medications, or prescription drugs, to sign an authorization, release, consent, or waiver permitting the disclosure of medical information, except as specified. The bill would also require pharmaceutical companies to adhere to specified procedures regarding the maintenance, disposal, and release of medical information and records.

(3) A violation of the Confidentiality of Medical Information Act constitutes a crime. Because a violation of this bill would be a crime, this bill would impose a state-mandated local program by creating a new crime.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 56.05 of the Civil Code is amended to 2 read:
- 3 56.05. For purposes of this part:
- 4 (a) "Authorization" means permission granted in accordance 5 with Section 56.11 or 56.21 for the disclosure of medical 6 information.
- 7 (b) "Authorized recipient" means any person who is 8 authorized to receive medical information pursuant to Section 9 56.10 or 56.20.
- 10 (c) "Contractor" means any person or entity that is a medical 11 group, independent practice association, pharmaceutical benefits 12 manager, or a medical service organization and is not a health care 13 service plan or provider of health care. "Contractor" does not

-3- AB 2191

include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code or pharmaceutical benefits managers licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

- (d) "Health care service plan" means any entity regulated pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).
- (e) "Licensed health care professional" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.
- (f) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.
- (g) "Patient" means any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains.
- (h) "Pharmaceutical company" means any company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs. "Pharmaceutical company" does not include a pharmaceutical benefits manager, as included in subdivision (c), or a provider of health care.
- (i) "Provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic

AB 2191 — 4 —

Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. "Provider of health care" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code.

- SEC. 2. Section 56.10 of the Civil Code, as added by Section 1.16 of Chapter 1068 of the Statutes of 2000, is amended to read: 56.10. (a) A provider of health care, health care service plan, pharmaceutical company, or contractor may not disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan without first obtaining an authorization, except as provided in subdivision (b) or (c).
- (b) A provider of health care, a health care service plan, pharmaceutical company, or a contractor shall disclose medical information if the disclosure is compelled by any of the following:
  - (1) By a court pursuant to an order of that court.
- (2) By a board, commission, or administrative agency for purposes of adjudication pursuant to its lawful authority.
- (3) By a party to a proceeding before a court or administrative agency pursuant to a subpoena, subpoena duces tecum, notice to appear served pursuant to Section 1987 of the Code of Civil Procedure, or any provision authorizing discovery in a proceeding before a court or administrative agency.
- (4) By a board, commission, or administrative agency pursuant to an investigative subpoena issued under Article 2 (commencing with Section 11180) of Chapter 2 of Part 1 of Division 3 of Title 2 of the Government Code.
- (5) By an arbitrator or arbitration panel, when arbitration is lawfully requested by either party, pursuant to a subpoena duces teeum issued under Section 1282.6 of the Code of Civil Procedure, or any other provision authorizing discovery in a proceeding before an arbitrator or arbitration panel.
- (6) By a search warrant lawfully issued to a governmental law enforcement agency.
- (7) By the patient or the patient's representative pursuant to Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

\_5 \_ AB 2191

(8) When otherwise specifically required by law.

1

2

3

4

5

6 7

8

9

10 11

12

13

14

15

16

17

18

20

21

22

23

24

25

2627

28

30

31

32

33

34

35

36 37

- (c) A provider of health care, health care service plan, or pharmaceutical company may disclose medical information as follows:
- (1) The information may be disclosed to providers of health eare, health eare service plans, pharmaceutical companies, contractors, or other health care professionals or facilities for purposes of diagnosis or treatment of the patient. This disclosure includes, in an emergency situation, the communication of patient information by radio transmission or other means between emergency medical personnel at the scene of an emergency, or in an emergency medical transport vehicle, and emergency medical personnel at a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.
- (2) The information may be disclosed to an insurer, employer, health care service plan, pharmaceutical company, hospital service plan, employee benefit plan, governmental authority, contractor, or any other person or entity responsible for paying for health care services rendered to the patient, to the extent necessary to allow responsibility for payment to be determined and payment to be made. If (A) the patient is, by reason of a comatose or other disabling medical condition, unable to consent to the disclosure of medical information and (B) no other arrangements have been made to pay for the health care services being rendered to the patient, the information may be disclosed to a governmental authority to the extent necessary to determine the patient's eligibility for, and to obtain, payment under a governmental program for health care services provided to the patient. The information may also be disclosed to another provider of health eare, health care service plan, or pharmaceutical company as necessary to assist the other provider, health care service plan, or pharmaceutical company in obtaining payment for health care services rendered to the patient.
- (3) The information may be disclosed to any person or entity that provides billing, claims management, medical data processing, or other administrative services for providers of health care, health care service plans, pharmaceutical companies, or for any of the persons or entities specified in paragraph (2). However,

AB 2191 — 6 —

information so disclosed may not be further disclosed by the recipient in any way that would violate this part.

- (4) The information may be disclosed to organized committees and agents of professional societies or of medical staffs of licensed hospitals, licensed health care service plans, professional standards review organizations, independent medical review organizations and their selected reviewers, utilization and quality control peer review organizations as established by Congress in Public Law 97-248 in 1982, contractors, or persons or organizations insuring, responsible for, or defending professional liability that a provider may incur, if the committees, agents, health care service plans, organizations, reviewers, contractors, or persons are engaged in reviewing the competence or qualifications of health care professionals or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges.
- (5) The information in the possession of a provider of health care, health care service plan, or pharmaceutical company may be reviewed by a private or public body responsible for licensing or accrediting the provider of health care, health care service plan, or pharmaceutical company. However, patient identifying medical information may not be removed from the premises, except as expressly permitted or required by law, nor shall that information be further disclosed by the recipient in any way that would violate this part.
- (6) The information may be disclosed to the county coroner in the course of an investigation by the coroner's office.
- (7) The information may be disclosed to public agencies, elinical investigators, including investigators conducting epidemiologic studies, health care research organizations, and accredited public or private nonprofit educational or health care institutions for bona fide research purposes. However, information so disclosed may not be further disclosed by the recipient in any way that would disclose the identity of a patient or violate this part.
- (8) A provider of health care, health care service plan, or pharmaceutical company that has created medical information as a result of employment related health care services to an employee conducted at the specific prior written request and expense of the employer may disclose to the employee's employer that part of the information that:

—7— AB 2191

(A) Is relevant in a lawsuit, arbitration, grievance, or other claim or challenge to which the employer and the employee are parties and in which the patient has placed in issue his or her medical history, mental or physical condition, or treatment, provided that information may only be used or disclosed in connection with that proceeding.

- (B) Describes functional limitations of the patient that may entitle the patient to leave from work for medical reasons or limit the patient's fitness to perform his or her present employment, provided that no statement of medical cause is included in the information disclosed.
- (9) Unless the provider of health care, health care service plan, or pharmaceutical company is notified in writing of an agreement by the sponsor, insurer, or administrator to the contrary, the information may be disclosed to a sponsor, insurer, or administrator of a group or individual insured or uninsured plan or policy that the patient seeks coverage by or benefits from, if the information was created by the provider of health care, health care service plan, or pharmaceutical company as the result of services conducted at the specific prior written request and expense of the sponsor, insurer, or administrator for the purpose of evaluating the application for coverage or benefits.
- (10) The information may be disclosed to a health care service plan by providers of health care that contract with the health care service plan and may be transferred among providers of health care that contract with the health care service plan, for the purpose of administering the health care service plan. Medical information may not otherwise be disclosed by a health care service plan, except in accordance with the provisions of this part.
- (11) This part does not prevent the disclosure by a provider of health care, health care service plan, or pharmaceutical company to an insurance institution, agent, or support organization, subject to Article 6.6 (commencing with Section 791) of Part 2 of Division 1 of the Insurance Code, of medical information if the insurance institution, agent, or support organization has complied with all requirements for obtaining the information pursuant to Article 6.6 (commencing with Section 791) of Part 2 of Division 1 of the Insurance Code.
- (12) The information relevant to the patient's condition, eare, and treatment may be disclosed to a probate court investigator

AB 2191 — 8 —

engaged in determining the need for an initial conservatorship or continuation of an existent conservatorship, if the patient is unable to give informed consent, or to a probate court investigator, probation officer, or domestic relations investigator engaged in determining the need for an initial guardianship or continuation of an existent guardianship.

- (13) The information may be disclosed to an organ procurement organization or a tissue bank processing the tissue of a decedent for transplantation into the body of another person, but only with respect to the donating decedent, for the purpose of aiding the transplant. For the purpose of this paragraph, the terms "tissue bank" and "tissue" have the same meaning as defined in Section 1635 of the Health and Safety Code.
- (14) The information may be disclosed when the disclosure is otherwise specifically authorized by law, such as the voluntary reporting, either directly or indirectly, to the federal Food and Drug Administration of adverse events related to drug products or medical device problems.
- (15) Basic information including the patient's name, city of residence, age, sex, and general condition may be disclosed to a state or federally recognized disaster relief organization for the purpose of responding to disaster welfare inquiries.
- (16) The information may be disclosed to a third party for purposes of encoding, encrypting, or otherwise anonymizing data. However, information so disclosed may not be further disclosed by the recipient in any way that would violate this part, including the unauthorized manipulation of coded or encrypted medical information that reveals individually identifiable medical information.
- (17) For purposes of disease management programs and services, as defined in Section 1399.901 of the Health and Safety Code, information may be disclosed as follows: (A) to an entity contracting with a health care service plan or the health care service plan's contractors to monitor or administer care of enrollees for a covered benefit, if the disease management services and care are authorized by a treating physician, or (B) to any disease management organization, as defined in Section 1399.900 of the Health and Safety Code, that complies fully with the physician authorization requirements of Section 1399.902 of the Health and Safety Code, if the health care service plan or its

\_9 \_ AB 2191

contractor provides or has provided a description of the disease management services to a treating physician or to the health care service plan's or contractor's network of physicians. This paragraph does not require physician authorization for the care or treatment of the adherents of a well-recognized church or religious denomination who depend solely upon prayer or spiritual means for healing in the practice of the religion of that church or denomination.

- (d) Except to the extent expressly authorized by the patient, enrollee, or subscriber or as provided by subdivisions (b) and (c), a provider of health care, health care service plan, pharmaceutical company, contractor, or corporation and its subsidiaries and affiliates may not intentionally share, sell, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient.
- (e) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), a contractor or corporation and its subsidiaries and affiliates may not further disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan or insurer or self-insured employer received under this section to a person or entity that is not engaged in providing direct health care services to the patient or his or her provider of health care or health care service plan or insurer or self-insured employer.
- (f) This section shall become operative January 1, 2003.

27 SEC. 3.

SEC. 2. Section 56.101 of the Civil Code is amended to read: 56.101. Every provider of health care, health care service plan, pharmaceutical company, or contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical records shall do so in a manner that preserves the confidentiality of the information contained therein. Any provider of health care, health care service plan, pharmaceutical company, or contractor who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of medical records shall be subject to the remedies and penalties provided under subdivisions (b) and (c) of Section 56.36.

39 SEC. 4.

SEC. 3. Section 56.102 is added to the Civil Code, to read:

AB 2191 — 10 —

 56.102. (a) A pharmaceutical company may not require a patient, as a condition of receiving pharmaceuticals, medications, or prescription drugs, to sign an authorization, release, consent, or waiver that would permit the disclosure of medical information that otherwise may not be disclosed under Section 56.10 or any other provision of law, unless the disclosure is for one of the following purposes:

- (1) Enrollment of the patient in a patient assistance program or prescription drug discount program.
  - (2) Enrollment of the patient in a clinical research project.
- (3) Prioritization of distribution to the patient of a prescription medicine in limited supply in the United States.
- (4) Response to an inquiry from the patient communicated in writing, by telephone, or by electronic mail.
- (b) Except as provided in subdivision (a) or Section 56.10, a pharmaceutical company may not disclose personal or medical information provided to it without first obtaining an authorization from the patient.
  - SEC. 4. Section 56.11 of the Civil Code is amended to read:
- 56.11. Any person or entity that wishes to obtain medical information pursuant to subdivision (a) of Section 56.10, other than a person or entity authorized to receive medical information pursuant to subdivision (b) or (c) of Section 56.10, shall obtain a valid authorization for the release of this information.

An authorization for the release of medical information by a provider of health care,—a health care service plan, pharmaceutical company, or contractor shall be valid if it:

- (a) Is handwritten by the person who signs it or is in typeface no smaller than 8-point type.
- (b) Is clearly separate from any other language present on the same page and is executed by a signature which serves no other purpose than to execute the authorization.
  - (c) Is signed and dated by one of the following:
- (1) The patient. A patient who is a minor may only sign an authorization for the release of medical information obtained by a provider of health care, health care service plan, pharmaceutical company, or contractor in the course of furnishing services to which the minor could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60).

— 11 — AB 2191

(2) The legal representative of the patient, if the patient is a minor or an incompetent. However, authorization may not be given under this subdivision for the disclosure of medical information obtained by the provider of health care, a health care service plan, pharmaceutical company, or—a contractor in the course of furnishing services to which a minor patient could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60).

- (3) The spouse of the patient or the person financially responsible for the patient, where the medical information is being sought for the sole purpose of processing an application for health insurance or for enrollment in a nonprofit hospital plan, a health care service plan, or an employee benefit plan, and where the patient is to be an enrolled spouse or dependent under the policy or plan.
- (4) The beneficiary or personal representative of a deceased patient.
- (d) States the specific uses and limitations on the types of medical information to be disclosed.
- (e) States the name or functions of the provider of health care, health care service plan, pharmaceutical company, or contractor that may disclose the medical information.
- (f) States the name or functions of the persons or entities authorized to receive the medical information.
- (g) States the specific uses and limitations on the use of the medical information by the persons or entities authorized to receive the medical information.
- (h) States a specific date after which the provider of health care, health care service plan, pharmaceutical company, or contractor is no longer authorized to disclose the medical information.
- (i) Advises the person signing the authorization of the right to receive a copy of the authorization.
- SEC. 5. Section 56.12 of the Civil Code is amended to read: 56.12. Upon demand by the patient or the person who signed an authorization, a provider of health care,—a health care service plan, pharmaceutical company, or contractor possessing the authorization shall furnish a true copy thereof.
- SEC. 6. Section 56.37 of the Civil Code is amended to read: 56.37. (a) A provider of health care, health care service plan, pharmaceutical company, or contractor may not require a patient,

AB 2191 — 12 —

as a condition of receiving health care services, including pharmaceuticals, medications, or prescription drugs, to sign an authorization, release, consent, or waiver that would permit the disclosure of medical information that otherwise may not be disclosed under Section 56.10 or any other provision of law. However, a health care service plan or disability insurer may require relevant enrollee or subscriber medical information as a condition of the medical underwriting process, if Sections 1374.7 and 1389.1 of the Health and Safety Code are strictly observed.

(b) Any waiver by a patient of the provisions of this part, except as authorized by Section 56.11 or 56.21 or subdivision (b) of Section 56.26, shall be deemed contrary to public policy and shall be unenforceable.

<del>SEC. 7.</del>

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.